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Feedback re: Medical Marijuana Regulations (NAC 453A)

DIRECTED COMMENTARY and SUGGESTIONS

Section 2:

Request revision. As currently written, the definition of batch could be taken to mean myriad different strains that happen to have been grown at the same time, which is illogical.

Suggested Language:

"Batch" means a specific strain of marijuana grown from one or more seeds or cuttings that are planted and harvested at the same time, and grown in the same location under the same conditions.

Section 36(3):

Request deletion or revision: Audited financials can easily cost upwards of $50,000. Especially given that the department of taxation will already be carefully examining financial records, there is no need to impose this cost on MMEs, which will in turn be forced to pass the cost along to patients in the form of higher prices. This is of particular burden in the first 2 years of operation when cash flows will be more precarious.

Ideally, this section will be deleted in its entirety. If deletion is not an option, then the following language is suggested:

Starting in the 3rd year of operation, and every 3rd year thereafter, a report of an audit by an independent certified public accountant of the annual financial statement submitted pursuant to subsection 2.

Section 40:

Request clarification: Please add clarification that there is no requirement that a MMEA be a registry card holder (e.g., a patient)

Section 42(2):

Request deletion or clarification: There should be no restriction that a MMEA be a RESIDENT of NV. Therefor, please either delete this provision, or specify that the business address of the medical marijuana establishment is sufficient to meet the requirement herein.

Section 51(1):

Request revision: As currently written, the implication is that every lot needs to be tested. If a large batch (same strain, same location, same conditions) is grown and harvested at the same time, the product will all be virtually identical. Thus, there should only need to be one test of that batch.

Suggested Language:

A medical marijuana establishment shall not sell or transport a lot of usable marijuana, edible marijuana products or marijuana-infused products until all required quality assurance testing has been completed. In the instance that the batch is larger than a single lot, the quality assurance testing on a sample from a single lot from the batch shall suffice, and the test results shall apply to all lots from that same batch.

Section 51(2):

Request revision: This clause currently reads, "A medical marijuana establishment shall ensure that all required quality assurance testing has been performed on a marijuana product each time after any marijuana the establishment is selling or transporting has changed form." Testing should only be required on the FINAL "form" of the product. A concentrate, for instance, could have largely the same cannabinoid profile yet be produced from different raw product, and certainly the process of manufacturing can change the profile of cannabis based products. Thus, testing should not be required of raw cannabis unless it is being sold in that form.

Suggested language

A medical marijuana establishment shall ensure that all required quality assurance testing has been performed on a marijuana product prior to selling or transporting that product to a dispensary to be sold.

Section 55(2)(b):

Request revision: As currently written, this suggests that EVERY person or organization who has a contract to do business with the medical marijuana establishment will need to possess a registration certificate, including but not limited to attorneys, accountants, janitorial staff, electricians, plumbers, alarm company personnel, etc. This is unwieldy, and does not distinguish between those who have OPERATIONAL involvement with the establishment, and those providing only ancillary supportive work or work product.

Suggested Language:

Be employed by or have a contract to provide services related to the operation of the establishment; or

Section 73/76

Request further consideration: Some suitable packaging (e.g., typical plastic bottles in which prescriptions are often dispensed) does not readily support labels of the size currently specified. Furthermore, some products are not suitable for child-resistant packing (e.g., a cannabis infused granola bar). Please consider different standards for labeling, and ideally clarify that we can use 1700(5)(b) which contains the substitute labeling statement, "Package Not Child Resistant."

Section 72(3)

Request revision: To facilitate the environmentally desirable use of greenhouses, while still preventing marijuana from being publicly visible, suggest modifying to reflect property lines rather than simply the 'outside' of a building

Suggested language:

Each cultivation facility shall ensure that any marijuana growing inside a building of the facility cannot be observed by the general public from outside the property line of the cultivation facility.

Section 79(1)(i)

Request revision: Serving size and number of servings will vary greatly based upon the patient and condition being treated (e.g., a child with chronic seizures vs. an obese individual with episodic severe pain). Suggest deleting the first portion of this clause, and revising accordingly.

Suggested language:

The total milligrams of active cannabinoids and terpenoids per unit as provided by the independent testing laboratory that tested the product;

Section 115

Request revision: In the context of medicine, the term, "laboratory based stability testing," has very specific connotations. Such testing costs $10's or even $100's of thousands of dollars, and months of time, for each product tested. This is untenable, and unnecessary, especially since there are no standards established for laboratory based stability testing of

dried marijuana products, and in the instance of edibles the expiration date should be based upon characteristics of the food items themselves.

Suggested language:

Each cultivation facility, facility for the production of edible marijuana products or marijuana-infused products, and medical marijuana dispensary shall, to assure that a medical marijuana product meets applicable standards of identity, strength, quality and purity at the time of use, ensure that the product is labeled, in the case of dried marijuana flower or concentrate, with the packed on date or manufactured on date, respectively, and in the case of infused or edible products, with the manufactured on date and an expiration date based on similar products not containing marijuana.

Section 121(1)

Request revision: It adds unnecessary cost, and unclear benefit, to require testing of harvested marijuana that is slated to be used for infused products or edibles, as those products require their own testing.

Suggested language:

Immediately before packaging raw marijuana for sale to a medical marijuana dispensary, a cultivation facility shall segregate the harvested marijuana into homogenized batches and select a random sample from each batch for testing by an independent testing laboratory. Harvested marijuana that is used for manufacturing subsequent marijuana products (e.g., infused products, edibles, etc.) does not require testing at this stage. Each cultivation facility must designate a person responsible for segregating all harvested marijuana into homogenized batches pursuant to this subsection. That person:

Section 132

Request deletion: As long as no diversion is taking place, which is a wholly different issue, there is no need for a limitation on production. Normal market forces of demand (from other legal Nevada medical marijuana establishments) are far more appropriate than regulation as drivers of supply. If the demand is not present, the supply will diminish naturally.

INDIRECT COMMENTARY: SUPPORT OR OPPOSITION TO OTHERS' PROPOSED AMENDMENTS

Fenmore, Craig, Jones, Vargas:

SUPPORT their rationale and suggested amendments as they pertain to:

Section 35
Section 72(3)
Sections 75-79
Section 137

Leland Parachini Steinberg (LPS):

SUPPORT their rationale and suggested amendments as they pertain to:

Section 35

Vicente Sederberg:

OPPOSE their rationale and suggested amendments as they pertain to:

Section 73(2). Specifically, their modification would require that plastic be used for packaging. We believe that the use of plastics should be limited where possible in favor of inert materials such as glass.

Section 131. They propose that 14% THC equates to 10 grams of THC. They are confused, as in reality the 14% is not based upon the total weight of the flower, but rather the oils contained therein. Your original language is adequate.

Clark County:

OPPOSE their rationale and suggested amendments as they pertain to:

New Stipulation: requiring that no dispensary shall purchase marijuana from another dispensary. These products will have all been tested by independent laboratories, and to the extent that one dispensary desires to purchase, and another to sell, a given product, there should be no prohibition of such sale and transfer of product.

Section 33(1): Your original language is adequate. To the extent that local jurisdictions wish to add their own additional stipulations, it is certainly within their right to do so.

Section 46(1): Your original language is adequate. To the extent that it is desirous to specify a time limit for written notice, I would suggest 10 business days as being more practical than 48 hours.

Section 72: Suggest modifying as reflected elsewhere in this document. Clark County's desire to add a phrase disallowing the cultivation facility to emit an odor that is detectable is far too broad, and is prohibitive. Elsewhere in the regulations you provide adequate guidance for the control of odor. Furthermore, "detection," as suggested by Clark

County is not defined. For instance, if a detection dog trained to detect marijuana were brought to the outside of a building, that is clearly a very different threshold of 'detectable' than the average member of the public walking by the property perimeter.

Todd Youren

SUPPORT his comment and suggested amendment as it relates to:

Section 62(1)(d)(1): The requirement that workspace be "sanitized" implies aseptic conditions, which is not realistic for cultivation. "Cleaned thoroughly," or some other such language, would be preferable. We concur with his statement that plants thrive best in conditions that include bacteria (just as humans do), which does not imply, "sanitized."

Max Del Real comments during the workshop on the 23rd

While I'm not innately opposed to some sort of regulation regarding building size for cultivation facilities, I'm not sure that I agree that a "hard cap" at 25,000 square feet makes sense. As you are aware, my partners and I intend to apply for licenses for a complete seed to sale operation, including at least 2 dispensaries. We believe we are going to cultivate to higher standards than many others, and we would like to be able to provide adequate supply of our own medical marijuana to our dispensaries and not be physically limited by an artificial constraint. I can easily envision starting off with one facility that might be 20-30,000 square feet, but on a property that is large enough that would support the build-out of an additional cultivation facility or facilities at the same site. Speaking of only our desired operation, and security considerations in particular, I would prefer to maintain all of our cultivation under one license at one location, rather than be subjected to obtaining additional licenses, at potential disparate locations. In general, the more sites, the greater the security risks, including the risk of diversion.

Thank you very much for your consideration of these suggestions. Please do not hesitate to contact me for clarification, or if I may be of service in any way.

Sincerely,

Shane A. Johnson, M.D.